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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,615	10/23/2003	Lewis G. Zirkle JR.	999Z CIP	5742

7590 10/04/2005
Stephen R. May
4067 Herald Sq. Pl.
Dublin, OH 43016

EXAMINER

STOKES, CANDICE CAPRI

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,615

Applicant(s)

ZIRKLE, LEWIS G.

Examiner

Candice C. Stokes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring (USPN 4,846,162) in view of Durham et al (USPN 6,168,595). Moehring discloses, “an elongated orthopedic nail 10 is dimensioned to substantially conform to the shape or the medullary canal of the bone to be fixed (FIG. 1)” (column 3, lines 16-19). “A first transverse aperture 20 extends through opposing wall portions of nail 10 at a second, opposite end 13 thereof spaced a predetermined longitudinal distance X from a second end of the nail. An optional second transverse aperture 22 extends through opposing wall portions of nail 10 spaced a second predetermined longitudinal distance Y from bight portion 16” (column 3, lines 25-32). “A handle 56 extending from shaft 58 may be provided. A lateral arm 60 extends from body 54 and terminates in an apertured socket 62” (column 4, lines 49-52). Moehring further discloses “a diameter-reducing sleeve (not shown) may be inserted into socket 62 and a drill bit 64 of a diameter to fit the sleeve is passed through the socket 62 and transversely through the bone using drill 44. The drill bit and sleeve are removed and a self-tapping proximal fastener 66 is engaged by the tip and threaded into the proximal opening formed by the drill in the bone” (column 4, lines 54-62). Furthermore, Durham et al show a proximal target arm 303 adjustably secured to a distal target arm 389 in FIG. 76. It would have been obvious to one having ordinary skill in the

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art at the time of the invention to incorporate a proximal and distal target arm as taught by Durham et al into the orthopedic nail disclosed by Moehring in order to provide a better means of locating and stabilizing an orthopedic intramedullary nail.

2) Claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring in view of Durham et al as applied to claims 1 above, and further in view of Kambin (USPN 5,395,317). Moehring and Durham et al in combination disclose an intermedullary nail as stated in Claim 1 however. they do not disclose a jig comprising a cannula. In a similar art, Kambin teaches that a "guide may take the form of jigs adapted to be secured to one cannula with bores arranged to slidably receive a guidewire or a cannula" (*see abstract*). With respect to Claims 4 and 9, Moehring discloses "a diameter-reducing sleeve (not shown) may be inserted into socket 62 and a drill bit 64 of a diameter to fit the sleeve is passed through the socket 62 and transversely through the bone using drill 44. The drill bit and sleeve are removed and a self-tapping proximal fastener 66 is engaged by the tip and threaded into the proximal opening formed by the drill in the bone. Because of the predetermined orientation of alignment jig 52 with nail 10, proximal fastener 66 will be aligned with aperture 20 and will pass therethrough" (column 4, lines 54-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a jig with a cannula into the intermedullary nail disclosed by Moehring and Durham et al in order to provide a means of engaging the bone prior to drilling of apertures.

3) Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring (USPN 4,846,162) in view of Durham et al. (USPN 6,168,595) as applied to Claim 1 above, and further in view of Davis (USPN 5,057,103). Moehring and Durham et al in combination teach

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an apparatus as stated in Claim 1, however they do not teach an apparatus with a device to remove an intermedullary nail from bone. In Davis' disclosure of a "compressive intramedullary nail" "a handle 37 and an extractor/impactor 39 are provided to aid in the insertion and the removal of the nail 13 from the bone" (column 3, lines 49-51). "The extractor/impactor 39 includes a rod 111, first and second stops 113, 115, and a throw weight 117. The rod 111 is threaded on both ends. The first end 119 is threaded into the first stop 113 while the second end 121 is adapted to be threaded into the inner member second end 69. The second end 121 of the rod 111 has a bore 122 therein to receive a guide wire 123 during insertion of the nail 13 into the bone 11. The second stop 115 and the throw weight 117 are free to move along the rod 111. The second stop 115 has a set screw 125 for locking the second stop to the rod 111 and preventing sliding movement. The throw weight 117 is located between the first and second stops 113, 115" (column 5, lines 59-68 and column 6, lines 1-3). The first stops acts as a cap at the end of the shaft. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate an extractor/impactor as taught by Davis in combination with the teachings of Moehring and Durham et al in order to provide a device to simplify removal of the intermedullary nail from bone.

4) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring (USPN 4,846,162) in view of Durham et al. (USPN 6,168,595) as applied to Claim 1 above, and further in view of Fujimori et al. (USPN 6,197,029). Moehring and Durham et al in combination teach an apparatus as stated in Claim 1, however they do not teach an apparatus consisting of an intermedullary nail with a plurality of longitudinal fins at the distal end. Fujimori et al. teach "an intramedullary nail in which a plurality of fins 26 which protrude radially are formed on the

outer circumference of the nail, providing firm internal fixation which makes the nail easy to operate" (*see abstract*). "FIG. 3 is an enlarged distal end view of the intramedullary nail 20. In this example, four fins with sharp tips 26 which extend from the distal part of the intramedullary nail 20 to an intermediate part are formed at unequal intervals. The external diameter of the fins 26 is 1.5 to 2 times the external diameter of the intramedullary 20. Furthermore, the length along which the fins 26 are formed is approximately 20 to 40% of the total length of the nail. However, these values are merely examples; and the spacing, number (plurality of fins must be formed), amount of protrusion, length of formation, etc. of the fins 26 are not limited to the values shown" (column 2, lines 53-64). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a plurality of fins as taught by Fujimori et al. to the on the distal end of the intermedullary nail as disclosed by a combination of teachings by Moehring and Durham et al in order to provide firm internal fixation which makes the nail easy to operate.

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Stokes whose telephone number is (571) 272-4714.

The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Candice C. Stokes


Cary E. O'Connor
Primary Examiner